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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/939,905	09/29/1997	MARK GIJZEN	76.105	4378
23117	7590	10/07/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/939,905	GIJZEN, MARK	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-12,14-29 and 36-39 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,8-12,14,15,17,19,21,23,25 and 27 is/are allowed.
- 6) ☒ Claim(s) 7,16,18,20,22,24,26,28,29, & 36-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

SW

DETAILED ACTION

Applicants' arguments, filed 6/30/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW MATTER

Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The NEW MATTER rejection of claims 36-39 is reiterated and maintained from the previous office action, mailed 3/31/05, and directed specifically to the "at least 19 contiguous nucleotides...SEQ ID NO: 2" limitation as necessitated by amendment. Applicants argue that this amendment is supported in the specification on page 33, line 10, to page 34, line 4, Figure 1, and Figure 5. Consideration of said page 33-34 citation reveals that no written support is found for "at least 19 contiguous nucleotides" or its equivalent nor such a segments from the nucleotides 1524-1610 of SEQ ID NO: 2. Likewise, Figures 1 and 5 cite specific primer segments but not the "at least 19 contiguous nucleotides..." limitation as generically set forth now in the claims. Applicants argue that primer prx9+ comprises 19 nucleotides and its usage is

exemplified in Figure 6 and on page 22 of the specification and allege that one of skill in the art may use any sequence within the 87 base pair region of 1524-1610 of SEQ ID NO: 2. In response, again a specific primer does not give written basis for the generic limitation as now claimed, especially the "at least" limitation therein. Also, applicants' argument that one of skill in the art may utilize any sequence within 1524-1610 of SEQ ID NO: 2 is not a statement in support of written basis. An ability of someone of skill in the art fails to disclose a written basis thereof as filed.

LACK OF SCOPE OF ENABLEMENT

Claims 7, 16, 18, 20, 22, 24, 26, 28, and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA molecule which has transcriptional activity which is the DNA molecule comprising nucleotides 1-1532 of SEQ ID NO: 2, does not reasonably provide enablement for other transcriptional regulatory activity possessing DNA molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

This rejection is reiterated and maintained from the previous office action, mailed 3/31/05. Applicants allege that a number of regulatory sequences, such as promoters, enhancers, etc. are instantly disclosed. In response this is acknowledged but not disclosed as to sequences per se and therefore lack the specific sequence disclosure that results in such activity. Thus, undue experimentation would be required as set forth in the previous office action to practice such undisclosed sequences. Functional wording for such regulatory sequences is insufficient to know what sequences actually

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would be made and used for such regulatory purposes for the nucleic acids as instantly claimed.

POTENTIAL INTERFERENCE

This is to inform applicants that the Request for Interference based on Vierling, Jr., et al. (P/N 6,586,583) is being held in abeyance at this time due to awaiting compliance with 37 CFR 41.102 regarding completion of examination. Any remaining rejection and/or objection indicates incomplete examination. An interference proceeding regarding an application is deemed to define a contested case subject to 37 CFR 41.102 as defined in 37 CFR 41.200, part (a).

Claims 1, 3, 4, 8-12, 14, 15, 17, 19, 21, 23, 25, and 27 are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 2, 2005

Ardin H. Marschel 10/2/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER